

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of :

LIPP et al.

Group Art Unit: TBA

Serial No.: TBA

Examiner: TBA

Filed: December 20, 2001

For: TRANSDERMAL SYSTEM THAT CONTAINS A NEW HIGHLY POTENT GESTAGEN

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Prior to initial examination, please amend the above-identified application as follows:

IN THE CLAIMS:

Please amend the claims as follows:

4. (Amended) Transdermal system according to claim 1, characterized by a content of 0.1 to 20% by weight, preferably 1 to 15% of (21S)-21-hydroxy-21-methyl-14,17-ethano-19-norpregna-4,9,15-triene-3,20-dione in the matrix.

5. (Amended) Transdermal system according to claim 1, wherein the matrix comprises at least one crystallization inhibitor.

7. (Amended) Transdermal system according to claim 1, characterized by an additional content of at least one of the following penetration intensifiers:

monovalent or multivalent alcohols such as ethanol, 1,2-propanediol or benzyl alcohol; saturated or unsaturated fatty alcohols with 8 to 18 carbon atoms, such as lauryl alcohol or cetyl alcohol; hydrocarbons such as mineral oil; saturated and unsaturated fatty acids with 8 to 18 carbon atoms such as stearic acid or oleic acid; fatty acid esters with up to 24 carbon atoms or dicarboxylic acid diesters with up to 24 carbon atoms, such as methyl ester, ethyl ester, isopropyl ester, butyl ester, sec-butyl ester, isobutyl ester, tert-butyl ester or monoglyceric acid ester of acetic acid, caproic acid, lauric acid, myristic acid, stearic acid and palmitic acid, phosphatide derivatives, such as lecithin, terpenes, urea and its derivatives or ethers, such as dimethyl isosorbide and diethylene glycol monoethyl ether.

9. (Amended) Transdermal system according to claim 1, characterized by an additional content of at least one estrogen such as estradiol, estriol, ethinylestradiol, derivatives thereof such as, for example, mono-esters and di-esters such as estradiol-3,17 β -dipropionate.

10. (Amended) Transdermal system according to claim 1, characterized by an additional content of at least one stabilizer, such as, for example, β -cyclodextrin.

REMARKS

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,


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Attorney Docket No.: SCH-1859

Date: December 20, 2001

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Please amend the claims as follows:

4. (Amended) Transdermal system according to claim 1 [one of claims 1 to 3], characterized by a content of 0.1 to 20% by weight, preferably 1 to 15% of (21S)-21-hydroxy-21-methyl-14,17-ethano-19-norpregna-4,9,15-triene-3,20-dione in the matrix.

5. (Amended) Transdermal system according to claim 1 [one of claims 1 to 4], wherein the matrix comprises at least one crystallization inhibitor.

7. (Amended) Transdermal system according to claim 1 [one of claims 1 to 6], characterized by an additional content of at least one of the following penetration intensifiers:

monovalent or multivalent alcohols such as ethanol, 1,2-propanediol or benzyl alcohol; saturated or unsaturated fatty alcohols with 8 to 18 carbon atoms, such as lauryl alcohol or cetyl alcohol; hydrocarbons such as mineral oil; saturated and unsaturated fatty acids with 8 to 18 carbon atoms such as stearic acid or oleic acid; fatty acid esters with up to 24 carbon atoms or dicarboxylic acid diesters with up to 24 carbon atoms, such as methyl ester, ethyl ester, isopropyl ester, butyl ester, sec-butyl ester, isobutyl ester, tert-butyl ester or monoglyceric acid ester of acetic acid, caproic acid, lauric acid, myristic acid, stearic acid and palmitic acid, phosphatide derivatives, such as lecithin, terpenes, urea and its derivatives or ethers, such as dimethyl isosorbide and diethylene glycol monoethyl ether.

9. (Amended) Transdermal system according to claim 1 [one of the preceding claims], characterized by an additional content of at least one estrogen such as estradiol, estriol, ethinylestradiol, derivatives thereof such as, for example, mono-esters and di-esters such as estradiol-3,17 β -dipropionate.

10. (Amended) Transdermal system according to claim 1 [one of the preceding claims], characterized by an additional content of at least one stabilizer, such as, for example, β -cyclodextrin.